UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte FRANK J. BUNICK, JOHN J. BURKE, TIMOTHY P. GILMOR and MICHELLE PAPALINI

Appeal No. 2006-0204
Application No. 09/896,052

ON BRIEF

Before SCHEINER, MILLS and GREEN, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

ON REMAND TO THE EXAMINER

This appeal involves claims to a texture masking oral dosage form. On consideration of the record, we find that this case is not in condition for a decision on appeal. Accordingly, we vacate the pending rejection under 35 U.S.C. § 103 and remand the application to the examiner to consider the following issues and to take appropriate action.[1]

[1] The term "vacate" in this context means to set aside or to void. When the Board vacates an examiner's rejection, the rejection is set aside and no longer exists.

The examiner rejected claims 1-25, all the claims pending in the application, as unpatentable under 35 U.S.C. §103(a). Claims 1 and 17 are representative of the claims on appeal, and read as follows:

1. A texture masking oral dosage form comprising

a) a unitary soft core comprising a plurality of active agent particles having an average size of greater than about 50 μm and

b) a brittle shell encasing the soft core, wherein the weight ratio of active agent particles to shell being from about 1.0:0.5 to about 1.0 in the texture masking oral dosage form.

17. A texture masking oral dosage form comprising

a) a unitary soft core comprising a plurality of active agent particles having an average size of greater than about 50 μm and

b) a brittle shell encasing the soft core, wherein the weight ratio of active agent particles to shell being from about 1.0:0.5 to about 1.0:15 and wherein the soft core has a hardness of about 1 to about 8 kp/cm^2 in the texture masking oral dosage form.

The examiner relies upon the following references:

Lee	6,060,078	May 9, 2000
Friend et al. (friend)	6,139,865	Oct. 31, 2000

Background

"Chewable dosage forms are often employed in the administration of active agents where it is impractical to provide a tablet for swallowing whole, where it is desirable to make an active agent available topically in the mouth or throat for both local effects or systemic absorption and to improve drug administration in pediatric and geriatric patients." Id., page 1. "It has been observed that particles in chewable dosage forms leave a gritty sensation in the

mouth that can be unpleasant, i.e., unpleasant mouthfeel. The term mouthfeel relates to the type of sensation or touch that a dosage form produces in the mouth . . . and is not concerned with the chemical stimulation of olfactory nerves or taste buds." Id. "In general, a gritty texture is undesirable. A smooth texture is preferred." Id.

The present invention is directed to "an oral dosage form for delivering active agents" (id., page 3), "that masks the grittiness of the active agents contained therein" (id.). The dosage form has "a soft core with [ ] active agent particles, which have an average size of greater than about 50 μm, and a brittle shell encasing the soft core, [ ] the weight ratio of drug particles to shell being from about 1.0:0.5 to about 1.0:15" (id.). "The active agent can be in the form of a fine powder, granule, or large crystal, and has an average particle size from about 20 to about 1000 μm, also from about 150 μm to about 500 μm. Typically, the active agent used in the present invention has an average size of greater than 50 μm" (id., page 7).

According to appellants, "the brittle [shell] of the present [dosage form] not only stabilizes the soft core, but it also provides a masking agent for the gritty texture of the active agent upon chewing" (id., page 3).

Discussion

The examiner rejected claims 1-25 under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Lee and Friend. According to the examiner, "Lee teaches a chewable pharmaceutical dosage form comprising [ ] a core containing an active ingredient, and an outer layer" which "demonstrates

improved organoleptic properties when chewed, such as taste" (Examiner's Answer, page 3). "The core may be in the form of a jelly . . . selected from a group that includes pectin" and "[t]he outer layer may take a variety of forms, including hard candy" (id.). "Acetaminophen is listed as a possible active ingredient in the core" but Lee "does not teach the use of ibuprofen in the [ ] dosage form" (id., page 4).

Friend is directed to microcapsule compositions "in which the taste of [a] drug contained therein is tastemasked" (Friend, column 1, lines 14-17). Friend's microcapsules range in size from approximately 30 μm to 800 μm (id., column 8, lines 31-36); may contain drugs including acetaminophen and ibuprofen (id., column 4, lines 34-35); and may be incorporated into chewable tablets (column 4, lines 56-60). It is not entirely clear from the record, but it appears that the examiner relies principally on those aspects of Friend's disclosure that concern the size of the microcapsules to make up any deficiencies in Lee (Examiner's Answer, page 4).

According to the examiner, "[i]t would be obvious to one of ordinary skill in the art to combine the teachings of Lee and Friend [ ] into the objects of the present invention" (Examiner's Answer, page 4) "to provide a pharmaceutical dosage form wherein the active ingredient is further taste-masked" (id.), because both references "deal with the administration[ ] of drugs in pharmaceutical compositions with improved organoleptic properties" (id.). The examiner asserts that "[t]he adjustment and optimization of parameters such as hardness of the soft core and the weight ratio of active agent particles are considered . . . to be

well within the purview of one of ordinary skill in the art" (id., page 5), "[t]herefore, claim limitations drawn to such features are not considered by the examiner to impart a patentable quality unto the instantly claimed invention" (id.).

Appellants argue essentially that Lee does not "disclose[ ] any particle size for anything, much less the claimed average particle size of the active agent particles" (Appeal Brief, page 6), and that Friend does nothing to make up this deficiency because Lee and Friend are not properly combinable (id., page 7). Appellants point out that the "excellent stability" of Lee's chewable tablets is attributed to the fact that the medicaments in the soft core are not subjected to high temperatures, but are combined with the core materials at room temperature (i.e., 25°C) (id., pages 7-8; Lee, column 3, lines 32-41). Friend's microcapsules, on the other hand, are formed by mixing a drug, a solvent and two polymeric materials, heating the mixture to 70°C or more to dissolve the polymeric materials in the solvent, and cooling the mixture at a rate and temperature sufficient to effect phase separation and microencapsulation of the drug (Appeal Brief, page 8; Friend, column 4, line 66 to column 5, line 50).

The examiner argues that "there is nothing in the Friend [ ] patent that requires that the incorporation of the disclosed encapsulated drug particles into oral dosage forms takes place at the same elevated temperature (80°C) at which the particles were prepared" (Examiner's Answer, page 6).

Maybe so, but as we understand appellants' position, it is that the drug in Friend's preparation is heated together with a solvent and two polymeric materials in order to form the microcapsules in the first place. We agree with

appellants that one skilled in the art would not have been led to incorporate Friend's microcapsules into the core of Lee's oral dosage form, particularly as Lee teaches that the "medicament . . . contained in the core[ ] [is] preferably . . . a medicament which is unstable to heat" (Lee, column 2, lines 5-6).

Appellants also emphasize that "there is [no] disclosure or suggestion for the claimed weight ratio of active agent particles to shell in any document cited by the Examiner" (Appeal Brief, pages 6-7), "[y]et it is the combination of claimed particle size of the active agent in the soft core and the claimed weight ratio of active agent particles to brittle shell that help to provide the texture masking of the present invention" (Reply Brief, page 2).

Nevertheless, Lee appears to be much more relevant to this issue than the examiner appreciated, in that Lee's dosage form provides texture masking in addition to masking the taste of bitter medicaments. Specifically, Lee teaches that "the conventional chewable tablet has problems . . . because of sandy taste in granular chew and chalky taste in mouth" (Lee, column 1, lines 33-35), but the "outer tasty chewable base" (i.e., the outer layer of the dosage form) imparts a "better chewing property . . . [to] the conventional tablets" (id., column 3, lines 56-58).

Where the difference between the claimed invention and the prior art is some range or other variable within the claims, appellants must show that the particular range or variable is critical, ideally by showing that the claimed range or variable achieves unexpected results relative to the prior art. In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990). The

discovery of an optimum value of a variable in a known process (or in this case, a composition) is normally obvious. In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). However, there is at least one exception to this general rule where "the parameter optimized was not recognized to be a result effective variable," In re Antonie, 559 F.2d 618, 621, 195 USPQ 6, 8 (CCPA 1977).

In our view, there is at least some evidence of record supporting the examiner's conclusion that the claimed invention would have been obvious to one of skill in the art, but that evidence has not been addressed or presented in a manner that gives appellants a full and fair opportunity to respond. Accordingly, we vacate the rejection of record, and remand the application to the examiner to take appropriate action. On return of the application, we encourage the examiner to reconsider Lee for all that it teaches, and to determine what was known in the art at the time of the invention with respect to such things as the physical parameters of drugs in chewable tablets, etc. Any further communication from the examiner containing a rejection of the claims should provide appellants with a full and fair opportunity to respond.

On this record, we find that the application is not in condition for a decision on appeal. Accordingly, the rejection of claims 1-25 under 35 U.S.C. § 103(a) is vacated, and the application is returned to the examiner to take appropriate action based on the issues discussed above.

VACATED and REMANDED

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